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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,222	10/20/2003	Yun-Fei Zhu	690068.481C2	2316

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EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,222	ZHU ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3-19-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-38 are pending.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 7, 9, 21 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claims 7 and 9 are incomplete for not reciting definitions for variables A_1-A_4. Therefore, it is not clear what the intended compound is.

b. Claim 21 lacks antecedent basis for reciting "*arylalkyl or substituted arylalkyl*" which is not recited in claim 14.

c. Claim 38 recites a method for treating "*sleep disorders*" which includes the treatment of conflicting disorders such as: narcolepsy and insomnia.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claims 32-36 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preventing pregnancy, does not reasonably provide enablement for a method of treating a sex-hormone related condition by antagonizing gonadotropin-releasing hormone (GnRH). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The breadth of the claims;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims:

Claim 32 recites: "*A method for antagonizing gonadotropin-releasing hormone...*" which (according to the specification) appears to cover the treatment of endometriosis, uterine

fibroids, polycystic ovarian disease, hirsutism, precocious puberty, short stature, prostate cancer, breast and ovarian cancers, gonadotrophe pituitary adenomas, sleep apnea, sleep disorders, irritable bowel syndrome, premenstrual syndrome, benign prostate hypertrophy, contraception and infertility. Such a scope includes the treatment of many diseases that have conflicting symptoms and/or manifestations.

Claim 33 recites: "*A method for treating a sex-hormone related condition...*" which basically has the same broad scope as claim 32.

Claims 34-36 and 38 depend on claim 33, but recite specific conditions.

The amount of direction or guidance presented:

The specification only outlines *in-vitro* bioassay methods, and does not indicate if any of the claimed compounds has been tested. There is no IC_{50} value disclosed for any compound. Thus, there is no evidence if the claimed compounds could antagonize GnRH, let alone treating related conditions. Furthermore, many diseases listed in the specification appear to have conflicting symptoms or manifestations. For example, agents that treat *endometriosis, uterine fibroids, polycystic ovarian* normally cause *hirsutism*, and not treating it. Likewise, agents that prevent pregnancy cannot treat infertility. The same rational is applied for the treatment of prostate cancer (or benign prostate hypertrophy) and the treatment of breast or ovarian cancer. The specification does not show a correlation between these conflicting diseases and the antagonizing effect on GnRh. Therefore, the specification does not provide guidance for a skilled clinician to treat many of these diseases or cancers that are allegedly related to GnRH.

The state of the prior art: Currently in the practice of medicine, the **agonists** of GnRH are used to treat endometriosis, and not the antagonists of GnRH. Also, agents that treat prostate cancer or tumor are not used to treat endometriosis, breast or ovarian cancer, etc. Thus, the state of the art does not support the scope of the method claimed herein.

The relative skill of those in the art: Even with the advanced training, the skilled clinician would have to engage in undue experimentation to establish data that would adequately support the use of the claimed compounds (GnRH antagonists) in the treatment of many conditions related to sex-hormone, but have conflicting symptoms. Such a task would require a tremendous amount of effort, time and resources.

The predictability or unpredictability of the art & The quantity of experimentation necessary: The pharmaceutical art has been known for its unpredictability due to various conflicting pathways, or biological factors that are sometimes genetically unique to individuals. In the instant case, the specification only outlines bioassay procedures without disclosing any evidence that the claimed compounds can antagonize GnRH or treating any related condtions other than preventing pregnancy. Thus, with such a limited teaching, the skilled clinician would have to carry out undue experimentation to use the claimed compounds in the methods recited in claims 32-36 and 38.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v.*

Eagle Mfg. Co., 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A **statutory type** (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-6, 8 and 10-38 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6, 8 and 10-38 of prior U.S. Patent No. **6,346,534 B1**. This is a double patenting rejection. The same compounds and corresponding composition as well as methods of treatment are claimed in both instances. Note, the instant claim 21 has the same scope as that of claim 21 in US'534 even though the dependency is different. It appears that the instant claim 21 should have depended on claim 20, and not claim 14.

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 7 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 9 of U.S. Patent No. **6,346,534 B1**. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the same compounds are claimed in both instances. Claims 7 and 9 of US'534 differ from the instant claims by reciting definitions of all variables. Given the same core of *pyrrolo[1,2-a]pyramid-7-one*, and variables recited, it would have been obvious to one skilled in the art to select the formulae claimed herein in view of those recited in US'534.

References cited on PTO-892

5. References cited on PTO-892 show state of the art. While they appear to teach relevant compounds, they do not have a publication date or filing date that antedates the effective filing date of this application.

No pending claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tamthom N. Truong
Examiner
Art Unit 1624

5-3-05

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